DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

Dyson

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 00-005

2. STATE: Minnesota

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
January 1, 2000

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:
42 CFR §440.120(a)

7. FEDERAL BUDGET IMPACT:
a. FFY 2000 $ 81,585
b. FFY 2001 $ 107,331

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Att. 3.1-A, pp. 44 - 44d
Att. 3.1-B, pp. 43-43d

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Same

10. SUBJECT OF AMENDMENT:
Services: Prescribed Drugs

11. GOVERNOR'S REVIEW *(Check One)*:

☒ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☐ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL:
Mary B Kennedy

13. TYPED NAME:
Mary B. Kennedy

14. TITLE:
Medicaid Director

15. DATE SUBMITTED:
March 30, 2000

16. RETURN TO:
Stephanie Schwartz
MN Dept of Human Services
444 Lafayette Road
Saint Paul, MN 55155-3853

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:
3/31/00

18. DATE APPROVED:
October 17, 2000

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:
January 1, 2000

20. SIGNATURE OF REGIONAL OFFICIAL:
Minnie Hood-Griffin Acting

21. TYPED NAME:
Cheryl A. Harris

22. TITLE:
Associate Regional Administrator
Division of Medicaid and Insurance Oversight

23. REMARKS:

FORM HCFA-179 (07-92)

Instructions on Back

MINNESOTA

MEDICAL ASSISTANCE

Federal Budget Impact of Proposed State Plan Amendment TN 00-05

Attachments 3.1-A/B: Prescribed Drugs

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1. Unless a practitioner writes that a recipient must receive a prescribed drug (rather than the generic equivalent), generic drugs must be dispensed if two items are met. TN 00-05 adds a third item: a generically equivalent drug is dispensed when the pharmacist or dispensing physician believes it is safely interchangeable with the prescribed drug. This addition provides another level of safety and scrutiny for recipients beyond the requirement that a generically equivalent drug must be approved and determined therapeutically equivalent by the Food and Drug Administration.

   This addition is not expected to have any fiscal impact, as it clarifies current policy.

2. TN 00-05 deletes agents used to promote smoking cessation from the list of drugs in the formulary requiring prior authorization.

   The Department anticipates that an additional $23,000 per month will be spent on smoking cessation product prescriptions, partially offset by a reduction of $5,500 per month in prior authorization costs. Therefore, the cost of this change is expected to be $17,500 per month. The anticipated Federal Fiscal Year costs are as follows:

$157,500 ($17,500 x 9) x 51.80%	=	$ 81,585 in FFY '00*
$210,000 ($17,500 x 12) x 51.11%	=	$107,331 in FFY '01

* January 1, 2000-September 30, 2000

12.a. Prescribed drugs.

The following providers are eligible for payment for dispensing prescribed drugs:

(1) A pharmacy that is licensed by the Minnesota Board of Pharmacy.
(2) An out of state pharmacy that complies with the licensing and certification requirements of the state in which it is located.
(3) A physician located in a local trade area where there is no Medicaid enrolled pharmacy. To be eligible for payment, the physician shall personally dispense the prescribed drug according to applicable Minnesota Statutes and shall adhere to the labeling requirements of the Minnesota Board of Pharmacy.
(4) A physician or nurse practitioner employed by or under contract with a community health board, for the purposes of communicable disease control.

The following limitations apply to pharmacy services:

(1) With the exception noted below, the prescribed drug must be a drug or compounded prescription that is made by a manufacturer that has a rebate with the Health Care Financing Administration (HCFA) and included in the Minnesota Department of Human Services drug formulary. The formulary is established in accordance with §1927 of the Social Security Act. See Drug Formulary.

A prescribed drug is covered if it has Investigational New Drug (IND) status with an IND number by the United States Food and Drug Administration (FDA), even though the manufacturer does not have a rebate with HCFA. When the prescribed drug receives FDA approval, the manufacturer must have a rebate agreement for the drug in order for the drug to be covered.

(2) A prescribed drug must be dispensed in the quantity specified on the prescription unless the pharmacy is using unit dose dispensing or the specified quantity is not available in the pharmacy when the prescription is dispensed. Only one dispensing fee is allowed for dispensing the quantity specified on the prescription.

12.a. Prescribed drugs. (continued)

(3) The dispensed quantity of a prescribed drug must not exceed a three-month supply.

(4) An initial or refill prescription for a maintenance drug shall be dispensed in not less than a 30-day supply unless the pharmacy is using unit dose dispensing. No additional dispensing fee shall be paid until that quantity is used by the recipient.

(5) Except as provided in item (6), coverage of the dispensing fee for a particular pharmacy or dispensing physician for a maintenance drug for a recipient is limited to one fee per 30-day supply.

(6) More than one dispensing fee per calendar month for a maintenance drug for a recipient is allowed if:

(a) the record kept by the pharmacist or dispensing physician documents that there is a significant chance of overdosage by the recipient if a larger quantity of drug is dispensed, and if the pharmacist or dispensing physician writes a statement of this reason on the prescription; or

(b) the drug is clozapine.

(7) A refill of a prescription must be authorized by the practitioner. Refilled prescriptions must be documented in the prescription file, initialed by the pharmacist who refills the prescription, and approved by the practitioner as consistent with accepted pharmacy practice under Minnesota Statutes.

(8) ~~Unless the practitioner has written in his or her own handwriting "Dispense as Written-Brand Necessary" or "DAW-Brand Necessary" on the prescription,~~ Generic drugs must be dispensed to recipients if:

12.a. Prescribed drugs. (continued)

(a) the generically equivalent drug is approved and is determined as therapeutically equivalent by the FDA; ~~and~~

(b) in the pharmacist's or dispensing physician's professional judgment, the generically equivalent drug is safely interchangeable with the prescribed drug;

(c) the charge for the substituted generically equivalent drug does not exceed the charge for the drug originally prescribed; and

(d) the practitioner has not written in his or her own handwriting "Dispense as Written-Brand Necessary" or "DAW-Brand Necessary" on the prescription.

(9) Over the counter medications must be dispensed in the manufacturer's unopened package, except that Sorbitol may be repackaged.

(10) The following limits apply to drugs dispensed under unit dose packaging:

(a) Dispensing fees for drugs dispensed in unit dose packaging shall not be paid more often than once per calendar month or when a minimum of 30 dosage units have been dispensed, whichever results in the lesser number of dispensing fees.

(b) Only one dispensing fee per calendar month will be paid for each maintenance drug, regardless of the type of unit dose system used or the number of times during the month the pharmacist dispenses the drug.

(c) An additional dispensing fee per prescription shall be paid to pharmacists using an in-pharmacy packaged unit dose system (except for over-the-counter [OTC] medications) approved by the Board of Pharmacy for the return of drugs when dispensing to recipients in a long-term care facility if:

12.a. Prescribed drugs. (continued)

(i) the pharmacy is registered with the Department by filing an addendum to the provider agreement;

(ii) a minimum 30-day supply of the drug is dispensed, although a lesser quantity may be dispensed for an acute course of medication therapy for a specified time period;

(iii) the national drug code from the drug stock container used to fill the unit dose package is identified to the Department;

(iv) the unit dose package containing the drug meets the packaging standards set forth in Minnesota Statutes that govern the return of unused drugs to the pharmacy for reuse and documentation that unit dose packaging meets permeability standards of the Board of Pharmacy; and

(v) the pharmacy provider credits the Department for the actual acquisition cost of all unused drugs that are eligible for return and reuse.

(11) Delivery charges for a drug are not covered.

Drug Formulary:

All drugs and compounded prescriptions made by a manufacturer that are ~~subject to~~ covered under a signed rebate agreement with HCFA are included in the drug formulary, with the following ~~two~~ three limitations ~~to~~ on coverage:

(1) The following drugs require prior authorization:
- (a) Alglucerase (Ceredase)
- (b) ~~Agents used to promote smoking cessation (includes patches, nasal sprays, gum, inhalers)~~
- ~~(c)~~ Botulinum Toxin Type A (Botox)
- ~~(d)~~ (c) Demeclocycline (Declomycin)
- ~~(e)~~ (d) Epoetin Alfa/Erythropoietion/EPO (Epogen and Procrit)

12.a. Prescribed drugs. (continued)

~~(f)~~ (e) Filgrastim/G-CSF (Neupogen)
~~(g)~~ (f) Granisetron (Kytril): for > 4 consecutive weeks continuous treatment
~~(h)~~ (g) Interferon Alfa-n3 (Alferon N)
~~(i)~~ (h) Interferon Gamma-1b (Actimmune)
~~(j)~~ (i) Lansoprazole (Prevacid): for > ~~8~~ 4 consecutive weeks continuous treatment
~~(k)~~ (j) Omeprazole (Prilosec): for > ~~8~~ 4 consecutive weeks continuous treatment
~~(l)~~ (k) Ondansetron (Zofran): for > 4 consecutive weeks continuous treatment
~~(m)~~ (l) Sargramostim/GM-CSF (Leukine and Prokine)
~~(n)~~ (m) Viagra (Sildenafil)

(2) The following categories of drugs subject to restriction under §1927(d)(2) are not covered:

(a) Agents when used for anorexia ~~or weight gain~~, except that medically necessary anorectics are covered for recipients previously diagnosed as having pickwickian syndrome and currently diagnosed as having diabetes and being morbidly obese.

(b) Agents when used to promote fertility.

(c) Agents when used for cosmetic purposes or hair growth.

(d) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(e) Drugs described in ~~§1703~~ §107(c)(3) of the Drug Amendments of 1962 and identical, similar, or related drugs (within the meaning of 21 CFR §310.6(b)(1) (DESI drugs)).

(3) ~~Other~~ The following categories of drugs ~~listed~~ subject to restriction under §1927(d)(2) are covered with limitations:

12.a. Prescribed drugs. (continued)

(a) Agents when used for the symptomatic relief of cough and colds must be listed in the Department's "Minnesota Health Care Programs Provider Manual," on a remittance advice message, or in a Department-issued provider update.

(b) Nonprescription drugs must be listed in the Department's "Health Care Programs Provider Manual," on a remittance advice message, or in a Department-issued provider update.

(c) Prescription vitamins and mineral products for children, pregnant and nursing women, and recipients with documented vitamin deficiencies. The limitations do not apply to fluoride treatments. Prenatal vitamins are restricted to pregnant and nursing women.

Notwithstanding the above paragraph, some vitamins and mineral products are available for the treatment or prevention of the following diseases:

(1) niacin;

(2) calcium and calcium/vitamin D; and

(3) generic preparations equivalent to Ocuvite.

12.a. Prescribed drugs.

The following providers are eligible for payment for dispensing prescribed drugs:

(1) A pharmacy that is licensed by the Minnesota Board of Pharmacy.
(2) An out of state pharmacy that complies with the licensing and certification requirements of the state in which it is located.
(3) A physician located in a local trade area where there is no Medicaid enrolled pharmacy. To be eligible for payment, the physician shall personally dispense the prescribed drug according to applicable Minnesota Statutes and shall adhere to the labeling requirements of the Minnesota Board of Pharmacy.
(4) A physician or nurse practitioner employed by or under contract with a community health board, for the purposes of communicable disease control.

The following limitations apply to pharmacy services:

(1) With the exception noted below, the prescribed drug must be a drug or compounded prescription that is made by a manufacturer that has a rebate with the Health Care Financing Administration (HCFA) and included in the Minnesota Department of Human Services drug formulary. The formulary is established in accordance with §1927 of the Social Security Act. See Drug Formulary.

A prescribed drug is covered if it has Investigational New Drug (IND) status with an IND number by the United States Food and Drug Administration (FDA), even though the manufacturer does not have a rebate with HCFA. When the prescribed drug receives FDA approval, the manufacturer must have a rebate agreement for the drug in order for the drug to be covered.

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12.a. Prescribed drugs. (continued)

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